Bard Peripheral Technologies
C.R. Bard, Inc.
13183 Harland Dr., N.E.
Covington, GA 30014

K014212

JAN 17 2002

BARD

510(k) SUMMARY OF SAFETY AND EFFECTIVENES INFORMATION

A. Submitter Information:

Submitter's Name: C.R. Bard, Inc., Peripheral Technologies Division
Submitter's Address: 13183 Harland Drive, Covington, GA 30014
Contact Person: Carol Vierling
Contact Person's Telephone Number: (770) 385-2347
Contact Person's FAX Number: (770) 385-2340
Date of Preparation: December 14, 2001

B. Device Name:

Bard® Conquest™ PTA Balloon Dilatation Catheter

C. Predicate Device:

Opti-Plast Centurion™ 5.5 Fr PTA Catheter

D. Device Description:

The Bard® Conquest™ PTA Balloon Dilatation Catheter is a coaxial lumen catheter with a balloon mounted on its distal tip. One lumen accommodates the insertion guidewire and the second provides a channel for inflation/deflation of the balloon. There are two radiopaque marker bands placed beneath the balloon to indicate its position within the vasculature.

E. Intended Use:

The Bard® Conquest™ PTA Balloon Dilatation Catheter is recommended for use in Percutaneous Transluminal Angioplasty of the femoral, iliac and renal arteries and for the treatment of obstructive lesions of native or synthetic arteriovenous dialysis fistulae. This catheter is not for use in coronary arteries.

F. Technological Characteristics Summary:

The Bard® Conquest™ PTA Balloon Dilatation Catheter is offered in 6, 7 or 8 Fr shaft diameters and shaft lengths of 50, 75 or 100cm, depending on balloon size. Various balloon diameters and lengths are available.

G. Performance Data:

Bench testing shows that the modified catheter is substantially equivalent to the predicate device, the Opti-Plast Centurion™ 5.5 Fr PTA Catheter.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 17 2002

Ms. Carol Vierling
Director, Regulatory Affairs
C.R. Bard, Inc.
Bard Peripheral Technologies
13183 Harland Drive, N.E.
Covington, GA 30014

Re: K014212
Trade Name: Bard® Conquest™ PTA Balloon Dilatation Catheter
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II (two)
Product Code: DQY
Dated: December 14, 2001
Received: December 21, 2001

Dear Ms. Vierling:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

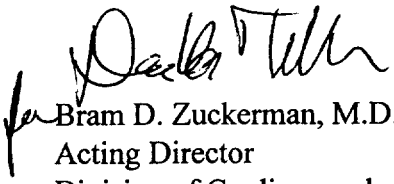
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4646. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,



Bram D. Zuckerman, M.D.
Acting Director
Division of Cardiovascular
and Respiratory Device
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

ATTACHMENT 5

Indications for Use Statement

Device Name	Bard® Conquest™ PTA Balloon Dilatation Catheter
Indications for Use	The Bard® Conquest™ PTA Balloon Dilatation Catheter is recommended for use in Percutaneous Transluminal Angioplasty of the femoral, iliac and renal arteries and for the treatment of obstructive lesions of native or synthetic arteriovenous dialysis fistulae. This catheter is not for use in coronary arteries.

PLEASE DO NOT WRITE BELOW THIS LINE—CONTINUE ON ANOTHER PAGE IF NEEDED.

Concurrence of CDRH, Office of Device Evaluation (ODE)

Division of Cardiovascular & Respiratory Devices
510(k) Number K012212

Prescription Use ✓ OR Over-The-Counter Use _____
(Per 21 CFR 801.109